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Epidemiological profile of diarrhaeagenic pathogens detected by the FilmArray gastrointestinal panel in children with gastroenteritis in Parma, northern Italy

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Background: Despite the substantial health burden of paediatric gastroenteritis, the etiologic profile of this disease remains poorly defined. Clinical laboratories currently employ different methodologies to detect the plethora of bacterial, viral and parasitic causes of gastroenteritis; a strategy that suffers from poor sensitivity, long turnaround times, and complicated ordering practices and workflows. This study shows the results obtained by a new multiplex PCR system (FilmArray Gastrointestinal Panel, BioFire Diagnostics, USA; bioMérieux, France) for the detection of diarrheagenic pathogens from stools in cases of childhood gastroenteritis.

Material/methods: From January to August 2016, 514 stool samples belonging to children (age range 3 days –13 years and 10 months, median age 2 years and 5 months) with gastroenteritis attending the University Hospital of Parma (360 inpatients and 154 outpatients) were submitted for routine diagnostic purpose to the FilmArray Gastrointestinal (FA-GI) Panel based on a clinical suspicion of bacterial and/or viral gastroenteric infection. The FA-GI Panel allows the rapid and simultaneous detection (1 h run time and 2 min preparation time) of 22 common diarrhoeal agents, as follows: *Campylobacter* sp., toxigenic *Clostridium difficile*, *Plesiomonas shigelloides*, *Salmonella* sp., *Vibrio* sp., *Vibrio cholerae*, *Yersinia enterocolitica*, enterotoxigenic *Escherichia coli* (ETEC), enteropathogenic *E. coli* (EPEC), *Shiga* toxin-producing *E. coli* (stx1/stx2, including *E. coli* O157), *Shigella*/enteroinvasive *E. coli* (EIEC), and enteroaggregative *E. coli* (EAEC), adenovirus F40/41, astrovirus, norovirus GI/GII,

rotavirus A, and sapovirus GI, GII, GIV, GV, *Cryptosporidium* sp.*, Cyclospora cayetanensis, Entamoeba histolytica,* and *Giardia lamblia*.

Results: The FA-GI Panel detected at least one agent in 247 (48%) of the 514 tested specimens. One hundred thirty-four (26.07%) specimens were positive for unexpected agents from the clinical suspicion. With the exception of *Plesiomonas shigelloides*, *Cyclospora cayetanensis*, and *Entamoeba histolytica,* all the targeted agents were detected at least once. Rotavirus (60 cases, 11.67%), EPEC (50 cases, 9.72%), *Clostridium difficile* (47 cases, 9.14%), sapovirus (33 cases, 6.42%), norovirus (26 cases, 5.05%) and EAEC (26 cases, 5.05%) were the six most commonly detected pathogens; the other agents were detected in less than 5% each. Out of the 247 positive specimens, 177 (71.65%) contained a single agent, whereas 70 (28.35%) contained multiple pathogens, accounting for 50 different combinations involving almost all pathogens detected. In particular, 52 specimens (74.29%) contained two agents, 13 (18.57%) three agents, 3 (4.29%) four agents, and 2 (2.85%) five agents.

Conclusions: The data reported herein impressively underline the wide spectrum of unexpected diarrheagenic pathogens circulating in children with gastroenteritis, and the high burden of co-infections in this disease, in most of the cases requiring hospitalization. A mutilplex approach with comprensive assay spectrum is pivotal to depict a complete picture of the etiology of gastroenteritis, to optimize the laboratory workload and improve the timeliness of diagnosis.